IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION

UNITED STATES OF AMERICA; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA, THE STATES OF CALIFORNIA, DELAWARE, CONNECTICUT, COLORADO, FLORIDA, GEORGIA, ILLINOIS, INDIANA, HAWAII, MICHIGAN, MONTANA, NEW MEXICO, NEW YORK, NEVADA, TENNESSEE, TEXAS, NEW JERSEY, RHODE ISLAND, OKLAHOMA, WISCONSIN, NORTH CAROLINA, AND MINNESOTA, THE CITY OF CHICAGO AND THE DISTRICT OF COLUMBIA *ex rel.* ELISA DICKSON, RELATOR Plaintiffs, v. BRISTOL MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S., L.L.C.; SANOFI-AVENTIS U.S., INC., AND SANOFI-SYNTHELABO, INC., Defendants.	§ §	Case No. 3:11-cv-246-DRH-SCW **RELATOR'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

MEMORANDUM IN SUPPORT OF RELATOR'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

For over a decade, Bristol Myers Squibb Company ("BMS") and Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, "Sanofi," and together with BMS, "Defendants") have engaged in a comprehensive scheme to defraud federal and state governments by illegally and deceptively promoting Plavix. Relator, Elisa Dickson, brought suit on behalf of the federal and state governments to recover the amounts over-paid for Plavix, and Defendants have moved to dismiss Relator's claims.

As set forth below, Relator has properly brought a claim under the False Claims Act ("FCA"). Relator's claims are not prohibited by the FCA's public disclosure bar. And, Relator's claims meet the pleading standard of Rule 9(b) by alleging the who, what, when, where, and how of the circumstances constituting fraud. Defendants' motion to dismiss should be denied.

ARGUMENT

As this Court has noted: "motions to dismiss . . . 'must receive careful scrutiny' and are 'not often granted.'" *United States v. City of Fairview Heights, Ill.*, 132 F. Supp. 2d 684, 686 (S.D. Ill. 2000) (quoting *Sidney S. Arst Co. v. Pipefitters Welfare Educ. Fund*, 25 F.3d 417, 420 (7th Cir. 1994)). This is because the issue is not whether a plaintiff will ultimately prevail on his claims but whether the claimant is entitled to offer evidence to support the claims. *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *abrogated on other grounds by Harlow v. Fitzgerald*, 457 U.S. 800 (1982). Here, dismissal is inappropriate.

I. RELATOR HAS STATED CLAIMS UNDER THE FALSE CLAIMS ACT.

Instead of focusing on the core of the FCA, Defendants attempt to distract the Court (and Relator) with judicially-created nuances. Whether a claim is "legally false" or "factually false" is beside the point. Rather, "the [FCA] was intended to reach all types of fraud, *without qualification*, that might result in financial loss to the Government." *United States v. Neifert-*

White Co., 390 U.S. 228, 232 (1968) (emphasis added). Thus, to plead a claim under 31 U.S.C. § 3729(a)(1), Relator must allege: "(1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false." *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 740-41 (7th Cir. 2007) (internal quotation marks and citation omitted), *overruled in part on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). Similarly, to plead a claim under 31 U.S.C. § 3729(a)(2),[1] Relator must allege: "(1) the defendant made a statement in order to receive money from the government, (2) the statement was false, and (3) the defendant knew it was false." *United States ex rel. Gross v. AIDS Research Alliance-Chi.*, 415 F.3d 601, 604 (7th Cir. 2005). Relator has plausibly plead the required elements for violations under both sections.

Defendants purposefully and knowingly trained their sales force to "confuse" [2] physicians about Plavix, even going so far as to hand-feed their sales representatives quotes that Defendants knew were fraudulent and/or misleading.[3] Because of the false information provided to the physicians, the physicians prescribed the drug when it was not reasonable and necessary for their patients and when a drastically cheaper non-prescription drug, aspirin, provided the same or better efficacy. The unreasonable and unnecessary prescribing of the drug caused the submission of claims that were statutorily ineligible for payment. The Defendants' pocketbooks were filled at the taxpayers' expense when the government paid the false claims. *See* 42 U.S.C. § 1395y(a)(1)(A).

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[1] Congress amended § 3729(a)(2) in 2009 and re-designated it as § 3729(a)(1)(B). *See* History to 31 U.S.C. § 3729. Courts in this Circuit continue to apply this same § 3729(a)(2) three-element standard for § 3729(a)(1)(B) claims. *See United States ex rel. Walner v. Northshore Univ. Healthsystem*, 660 F. Supp. 2d 891, 896 n.4 (N.D. Ill. 2009).

[2] Dkt. No. 38 ¶ 21; Dkt. No. 38-1 ¶ 29.

[3] Dkt. No. 38 ¶¶ 20-21; Dkt. No. 38-1 ¶¶ 18-19, 29.

A. The Government Should Not Pay Claims For Prescription Drugs Unless They Are Reasonable And Necessary For Each Individual Patient.

The Medicare statute could not be any clearer. "[N]o payment may be made . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A).[4] This express condition links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary." *Id*. Courts at the highest level have recognized this prerequisite to payment of Medicare claims. *See, e.g.*, *Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (finding that the Medicare act "precludes reimbursement" for drugs that are not reasonable and necessary); *United Seniors Ass'n, Inc. v. Shalala*, 182 F.3d 965, 967 (D.C. Cir. 1999) ("If a service is deemed not to have been reasonable and necessary, Medicare will not make payment and the doctor generally is prohibited from charging the patient."); *Mount Sinai Hosp. of Greater Miami, Inc. v. Weinberger*, 517 F.2d 329, 334 (5th Cir. 1975) (explaining that § 1395y controls whether particular services are excluded from Medicare coverage). Because submitting a claim for reimbursement is stating that the prescribed treatment is reasonable and necessary for the patient, if the treatment is not reasonable and necessary, then the submission is a "false claim." *See In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 346 (D. Conn. 2004) (holding defendants, by submitting claims forms, implicitly certified compliance with the Medicare statute and "to the extent that the forms included requests for payment for services that were not reasonable and necessary, the claims were legally false under an implied certification theory").[5] Defendants' fraudulent actions caused countless physicians to cross this line.

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[4] This express condition of payment also applies to claims submitted under Medicare Part D. *See* 42 U.S.C. § 1395w-102(e)(3)(A).

[5] District courts within the Seventh Circuit have recognized viable FCA claims based on an "implied certification theory." *See, e.g., United States ex rel. King v. F.E. Moran, Inc.*, No 00C3877, 2002 WL 2003219, at *11 & n.2 (N.D. Ill. Aug. 29, 2002) (rejecting the Defendant's "suggestion that the implied certification theory is not valid under the FCA" and noting that "[t]o succeed under this theory, a plaintiff must show that compliance with the

Indeed, physicians are the taxpayers' first defense in preventing government payment for expensive prescription drugs—such as Plavix—when they are not reasonable and necessary. Even for drugs that are FDA-approved for certain indications, the physician must determine *for each individual patient* whether a drug is reasonable and necessary. *See, e.g.*, Medicare Benefit Policy Manual, Chapter 15 § 50.4.1 (noting that Medicare "may pay for the use of an FDA approved drug" if "[i]t is reasonable and necessary for the individual patient"); *see also United States ex rel. Bennett v. Boston Scientific Corp.*, No. H-07-2467, 2011 WL 1231577, at *26 (S.D. Tex. Mar. 31, 2011) ("The decision on medical necessity is made by individual physicians exercising independent professional judgment based on the knowledge of their particular patients."); *Rush v. Parham*, 625 F.2d 1150, 1156 (5th Cir. 1980) (recognizing that "the private physician [has] the primary responsibility of determining what treatment should be made available to his patients"). And, just because a drug is FDA approved does not mean that it is "reasonable and necessary." *See Almy v. Sebelius*, 749 F. Supp. 2d 315, 330-31 (D. Md. 2010) (recognizing that FDA approval is only one factor in determining whether an item or service is reasonable and necessary).[6] The necessity of a drug is a critical consideration of the prescribing physician, so critical that courts often "employ what is known as the 'treating physician' rule,

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relevant statutes and regulations was a condition of receiving payment" (citations omitted)); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 614 (N.D. Ill. 2003) ("Under [an implied certification theory], a claim made in contravention of statutory or regulatory requirements may be deemed false under the FCA in cases where the defendant's certification of compliance with the statutes and regulations in question is a condition of receiving funds from the Government." (internal quotation marks and citation omitted)). Notably, the Second, Third, Sixth, Ninth, Tenth, Eleventh and District of Columbia Circuits all have expressly recognized the implied false certification theory under the FCA. *See Mikes v. Straus*, 274 F.3d 687, 699 (2d. Cir. 2001); *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 306 (3d Cir. 2011); *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002); *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 996–98 (9th Cir. 2010); *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217-18 (10th Cir. 2008); *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005); *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1266-69 (D.C. Cir. 2010).

[6] Defendants misconstrue Relator's allegations of false claims. *See* Dkt. No. 44 ¶ 11. Relator's claims in no way challenge the FDA's approval of Plavix. Rather, Relator witnessed (and now informs the government) that Defendants fraudulently promoted Plavix as being the only option for certain indications thereby causing physicians to submit false claims. For that reason, instead of being "exactly on point," *United States ex rel. Polanksy v. Pfizer*, No. 04 Civ. 0704(BMC), 2012 WL 5595933 (E.D.N.Y. Nov. 15, 2012), entirely misses the point.

which provides that with respect to medical necessity, the judgment of the treating physician should be given 'extra weight.'" *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1032 (D. Nev. 2006) (citation omitted). Here, Defendants' duplicity deprived physicians of the information necessary to make that decision for each patient.

B. Defendants' Scheme To Falsely Promote Plavix Caused The Submission Of False Claims.

Defendants instructed their sales force to present physicians with fraudulent information regarding the safety and efficacy of Plavix with the purpose of convincing physicians that Plavix was reasonable and necessary when it was not.[7] Defendants instructed their sales force to promote Plavix as comparably safe and more efficacious than a cheaper and safer over-the-counter aspirin pill, knowing this information to be false.[8] Despite the non-significant efficacy data in the CAPRIE trial for stroke patients, Defendants instructed sales representatives to present pamphlets to physicians claiming there was "proven efficacy" of Plavix over aspirin in ischemic stroke patients.[9] Defendants similarly trained their sales representatives to promote Plavix as being superior to aspirin in stroke patients, despite the 2010 ASA guidelines that provided a higher recommendation for aspirin compared to Plavix.[10] In addition, despite the ASA's finding that "there have been no clinical trials to indicate that switching anti-platelet agents reduces the risk for subsequent events," Defendants instructed their sales force to encourage physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin.[11] Finally, Defendants instructed their sales force to present false statements

[7] Dkt. No. 38 ¶¶ 15, 19-23; Dkt. No. 38-1 ¶¶ 36-37.
[8] Dkt. No. 38 ¶¶ 19-23, 49-53; Dkt. No. 38-1 ¶¶ 18-19, 22, 29, 36- 37.
[9] Dkt. No. 38 ¶¶ 20, 49-52; Dkt. No. 38-1 ¶ 16.
[10] Dkt. No. 38 ¶ 51; Dkt. No. 38-1 ¶¶ 17-18.
[11] Dkt. No. 38-1 ¶ 19-20; *see also* Dkt. No. 38 ¶¶ 20, 52.

regarding the PRoFESS trial in order to "confuse physicians and make them believe Aggrenox was inferior to Plavix."[12]

These misrepresentations "left many physicians with the false impression that Plavix was essentially the *only option* for effective patient care in a host of contexts."[13] It is in this light that they prescribed Plavix, thus implicitly certifying to the government that this drug was reasonable and necessary. The fact, however, is that Plavix was not the prescribing physicians' only option. Had Defendants told the truth, physicians would have seen Plavix for what it is—an expensive platelet inhibitor that is no more effective – and much more dangerous – than a daily aspirin. With Plavix fully illuminated—particularly considering the enhanced risk of side effects, the infancy of the drug, the lack of sufficient testing, the inconsistent results, and the absence of enhanced efficacy over aspirin—physicians would not have prescribed Plavix as frequently.[14] This reduced number of prescriptions would have resulted in fewer false claims that Plavix was reasonable and necessary when being submitted for Medicare reimbursement. Further, Defendants specifically instructed their sales force (including Relator) to target physicians "whose patients relied upon public assistance programs such as Medicaid" and Medicare.[15]

Defendants causing physicians to certify that Plavix was reasonable and necessary when it was not is actionable under the FCA. *See, e.g., United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 389 (1st Cir. 2011) (determining that a defendant need not be the entity that actually submits the false claim, when the non-submitting entity "knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid"); *Mason v. Medline Indus., Inc.*, 731 F. Supp. 2d 730, 738 (N.D. Ill. 2010) (recognizing

[12] Dkt. No. 38-1 ¶ 29; *see also* Dkt. No. 38 ¶ 21.
[13] Dkt. No. 38-1 ¶ 37 (emphasis added).
[14] Dkt. No. 38 ¶ 71; Dkt. No. 38-1 ¶ 37.
[15] Dkt. No. 38 ¶ 22; Dkt. No. 38-1 ¶ 32.

that the FCA reaches claims that are rendered false by one party, but submitted to the government by another).[16]

This result is confirmed by case law. For example, in *Strom ex rel. United States v. Scois, Inc.*, 676 F. Supp. 2d 884 (N.D. Cal. 2009), the Northern District of California found a viable FCA action where a company's false promotion of a drug caused it to be prescribed when the drug was not reasonable and necessary. *Id*. at 891. The finding was premised on the court's recognition that "a prescription . . . in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement." *Id*. (quoting 42 U.S.C. § 1395y). Importantly, in reaching this determination, the court did not consider whether there might be some instances where a physician could properly prescribe the drug at issue. Rather, it reached its decision based on the notion that the defendants' misrepresentations deprived the physicians of the opportunity to "make considered medical judgments." *Id*. n.2.

Similarly, the Second Amended Complaint ("SAC") alleges that "[Defendants'] actions caused physicians to submit numerous prescriptions for Plavix for reimbursement by Government Payors. [Defendants'] actions knowingly caused physicians . . . to either expressly or impliedly make false certifications about Plavix's efficacy or necessity for the patient's treatment."[17] That there may be some instances where Plavix can be properly prescribed does not mean that Relator has failed to assert an action under the FCA. Here, like in *Strom*, Relator's "allegations suggest that the only reason *any* doctor prescribed [the drug at issue] was because of

[16] What is more, although Medicare payments are not expressly conditioned on a drug being economical, a physician must consider a drug's economics when determining whether it is reasonable and necessary. The Medicare statute requires a physician "to assure . . . that services or items ordered . . . will be provided economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1). For that reason, by submitting claims for Plavix, the prescribing physicians assured the government that Plavix was provided economically—a claim prescribing physicians only made because Defendants convinced them that Plavix was the sole option for their patients. In truth, if an option at all, Plavix is the most expensive option—400 times more expensive than a daily aspirin to be precise. Any statement, then, that Plavix is "provided economically" is plainly false given its lack of enhanced effectiveness and dangerous side effects.

[17] Dkt. No. 38 ¶ 71; Dkt. No. 38-1 ¶ 37.

Defendants' earlier promotion," and that the doctors "did not, in fact, make considered medical judgments" because they had been "duped." *Id*. at 891-92, 894 & n.4 (noting that the physicians "were told that certain medical evidence existed, when in fact it did not").[18] Therefore, accepting Relator's allegations as true and drawing all reasonable inferences in her favor (as this Court must), Relator has set forth a cognizable claim under the FCA. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) ("[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is remote and unlikely." (internal quotation marks and citation omitted)).

II. RELATOR'S CLAIMS ARE NOT BARRED BECAUSE RELATOR IS THE ORIGINAL SOURCE OF UNIQUE ALLEGATIONS THAT ARE NOT BASED UPON OR SUBSTANTIALLY THE SAME AS PUBLIC DISCLOSURES.

Relator's claims are precisely what the False Claims Act encourages—"lawsuits by relators who have firsthand knowledge of fraud against the government." *Glaser*, 570 F.3d at 910. And, contrary to Defendants' bald assertions, Relator did not "merely re-hash" prior publicly disclosed allegations.[19] As a member of Defendants' sales force for almost a decade, Relator witnessed firsthand an ongoing scheme to defraud physicians into prescribing Plavix even though the drug was no more effective than a cheaper and safer aspirin.[20] Defendants fueled this scheme by training and instructing their sales representatives (including Relator) to "confuse"[21] physicians and to "focus sales calls on physicians and prescribers whose patients

[18] The mere fact that the government paid claims for Plavix is inapposite because the FCA's fundamental purpose is to recover monies that the government reimbursed as a result of a defendant's fraudulent conduct. *See United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) ("The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers; the False Claims Act does this by insisting that persons who send bills to the Treasury tell the truth."). As Justice Holmes perhaps best put it, "[m]en must turn square corners when they deal with the Government." *Rock Island, Ark. & La. R.R. v. United States*, 254 U.S. 141, 143 (1920).

[19] Dkt. No. 44 at 12-13.

[20] *See, e.g.*, Dkt. No. 38 ¶¶ 3, 19-20, 23, 32, 46-60; Dkt. No. 38-1 ¶¶ 18-19, 22, 29, 33, 36, 37.

[21] *See, e.g.*, Dkt. No. 38 ¶¶ 21, 59; Dkt. No. 38-1 ¶ 29.

relied on"[22] Medicaid and Medicare—doctors with "an inherent willingness to prescribe more expensive drugs."[23] This information—which underlies Relator's claim—was not publicly disclosed prior to this lawsuit, and even if it was publicly disclosed, Relator is an original source of this information. Accordingly, this Court should deny Defendants' motion to dismiss.

A. The "Critical Elements" Of Relator's Claim Were Not Publicly Disclosed.

"'[P]ublic disclosure' exists under § 3730(e)(4)(A) when the *critical elements exposing the transaction as fraudulent* are placed in the public domain." *United States ex rel. Feingold v. AdminaStar Fed., Inc.*, 324 F.3d 492, 495 (7th Cir. 2003) (emphasis added).[24] The Seventh Circuit, however, has said almost nothing on what exactly constitutes publicly disclosed material under the FCA. But, it is clear that a "public disclosure" must be sufficient to "bring to the attention of the relevant authority that there has been a false claim against the government." *AdminaStar*, 324 F.3d at 495. The "critical elements" then, must be at least the elements of a false claim actionable under the FCA. And importantly, an FCA claim is actionable only if a person (or entity) "*knowingly* presents' [or causes to be presented] to the United States government 'a false or fraudulent claim for payment." *Hindo v. Univ. of Health Scis. / The Chi. Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995) (emphasis added) (internal quotation marks and

[22] *See, e.g.*, Dkt. No. 38 ¶¶ 3, 23, 61; Dkt. No. 38-1 ¶ 32.

[23] *See, e.g.*, Dkt. No. 38 ¶ 61; Dkt. No. 38-1 ¶ 33.

[24] On March 23, 2010, Congress amended 31 U.S.C. § 3730(e)(4)(A) as a part of the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010). The post-PPACA public disclosure bar clearly applies to Defendants' false claims submitted on or after March 23, 2010. It is less clear whether the pre-PPACA or post-PPACA language applies to false claims submitted prior to PPACA, and the Seventh Circuit has not decided this issue. Some courts have found that the determining point is when the false claims were made. *See, e.g., United States ex rel. Osheroff v. Humana, Inc.*, No. 10-24486-CV-SCOLA, 2012 WL 4479072, at *4 n.8 (S.D. Fla. Sept. 28, 2012). Others, including the Supreme Court, have suggested that the date the FCA case was filed is the determinative factor. *See, e.g., Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010) (applying the statute "as it existed at the time the case was argued"); *United States ex rel. Sanchez v. Abuabara*, No. 10-61673-CIV, 2012 WL 1999527, at *2 n.1 (S.D. Fla. June 4, 2012) ("Since the suit in this case was filed many months after [PPACA] was signed into law, this Court will apply the amended language."). Because this action was filed after PPACA, this Court may well find that the post-PPACA statute applies with respect to all of Relator's claims. Nevertheless, no matter what statute applies, Relator's claims are not prohibited by the public disclosure bar.

citation omitted). None of Defendants' references, taken separately or together, disclose this "critical element."

At most, the resources cited by Defendants suggest that Defendants were negligent—not fraudulent—in their promotion of Plavix.[25] The *Hall* complaint, for example, only alleges that Defendants knew, "or if they had paid attention to the findings of their own studies, *should have known*, that Plavix was not more efficacious than aspirin."[26] As publicly disclosed, Defendants' promotion of Plavix may have been a mistake or perhaps the result of drug representatives acting outside Defendants' authority. But nothing in the *Hall* complaint confirms that Defendants acted fraudulently.

Similarly, the government reports and letters reveal nothing more than the well-known facts that the "CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superior efficacy over aspirin" and that statements suggesting otherwise "are misleading."[27] And, although some of the news articles hint at Defendants' general bad acts,[28]

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[25] What is more, several of Defendants' cited references categorically do not constitute public disclosures, at least for some of Relator's claims. For false claims governed by the pre-PPACA statute, the public disclosure bar can be triggered by allegations in "[1] a criminal, civil, or administrative hearing, [2] in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or [3] from the news media." 31 U.S.C. § 3730(e)(4)(A) (pre-PPACA). On its face, this language would appear to include Defendants' references. The post-PPACA statute, however, limits public disclosures to those (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media." 31 U.S.C. § 3730(e)(4)(A) (post-PPACA). Thus, for claims governed by the post-PPACA statute, Defendants' primary reference—the *Hall* complaint—along with Defendants Exhibits H and I do not constitute public disclosures because they are not Federal cases where the Government is a party.

[26] *See* Dkt. No. 44-2, Second Amended Complaint ¶ 14, *Hall v. Bristol-Meyers Squibb Co.*, No. 06-5203 (D.N.J. May 1, 2009); *see also id.* ¶ 68 ("The Defendants knew *or should have known* that consumers such as the Plaintiff would suffer injury or die as a result of the Defendants' failure to exercise reasonable and ordinary care." (emphasis added)). Tellingly, the *Hall* complaint only alleges claims for defective design, manufacturing defect, failure to warn, negligence, negligent misrepresentation, and violations of the Florida Unfair Deceptive Trade Practices Act. As such, the Hall plaintiffs had no need to plead that Defendants "had actual knowledge," "acted in deliberate ignorance," or "acted in reckless disregard" of the truth about Plavix—allegations that are the heart of a FCA claim. *See, e.g.*, *Hindo*, 65 F.3d at 613.

[27] *See, e.g.*, Div. of Drug Mktg. & Commc'ns, FDA, Untitled Letter, May 9, 2001, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplanceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166467.pdf (last visited Jan. 14, 2013).

they do not expose the particular scheme at issue here (i.e., training sales representatives to "confuse" and mislead doctors), and, therefore, do not trigger the public disclosure bar. This "very high level of generality is inappropriate" to establish public disclosure. *United States ex rel. Goldberg v. Rush Univ. Med. Ctr.*, 680 F.3d 933, 935 (7th Cir. 2012).

This is no trivial point. "Innocent mistakes or negligence are not actionable" under the FCA. *Hindo*, 65 F.3d at 613. "[W]hat constitutes the offense is not intent to deceive but knowing presentation of a claim that is either fraudulent or simply false. The requisite intent is the knowing presentation of what is known to be false. In short, the claim must be a lie." *Id.* (internal quotation marks and citation omitted). And, in contrast to all prior public disclosures, Relator's allegations alone expose this "critical element."

The SAC exposed that Defendants knew the truth about Plavix and nevertheless instructed their sales representatives to "confuse" and mislead doctors into prescribing the drug even when it was unreasonable and unnecessary to do so. For example, "[a]s a member of the sales force, [Relator] was instructed to present the PRoFESS data in a manner designed to confuse physicians and make them believe that Aggrenox was inferior to Plavix,"[29] "to also state that 'it should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients,"[30] to "promote[] Plavix as being superior to aspirin in stroke patients,"[31] "to encourage physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin,"[32] and "to focus sales calls on physicians and prescribers whose patients relied

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[28] *See, e.g.*, Dkt. No. 44-3 (disclosing generally that Defendants were "lying to physicians and to the public about the safety and efficacy of Plavix" but noting that the legal complaint that the article discusses only alleged claims for "strict products liability, manufacturing defect, failure to warn and negligence against the defendants"); Dkt. No. 44-5 (merely reciting allegations regarding Plavix and providing one reporter's unsubstantiated speculation).

[29] Dkt. No. 38-1 ¶ 29; *see also* Dkt. No. 38 ¶ 21.

[30] Dkt. No. 38-1 ¶ 29; *see also* Dkt. No. 38 ¶ 21.

[31] Dkt. No. 38-1 ¶ 18; *see also* Dkt. No. 38 ¶ 20.

[32] Dkt. No. 38-1 ¶ 19; *see also* Dkt. No. 38 ¶ 20.

upon" Government Payors.[33] Further, "Sanofi *require[d]* that [the sales force] promote Plavix as comparably safe to aspirin based on the CAPRIE study even though the CAPRIE study compared Plavix to a more toxic dose of aspirin that is not regularly prescribed today."[34]

As these allegations show, this is not the case where Relator merely has provided additional evidence of a previously disclosed fraud. The fact is that Relator is the first person to inform the government that Defendants affirmatively knew the truth about Plavix, disregarded that truth, and hatched a plan to use its sales force to dupe doctors into prescribing Plavix—even after the FDA told them to stop wrongfully promoting Plavix. Without these critical elements—the elements that expose Defendants' fraudulent scheme—there is no claim under the FCA. *See United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[I]t is impossible to meaningfully discuss falsity without implicating the knowledge requirement.").

B. Relator's Allegations Are Not "Based Upon" Or "Substantially The Same As" Public Disclosures.

Even if the Court finds that the skeleton allegations of Defendants' general wrongdoing constitute public disclosure (which they do not), the Court must then ask whether Relator's action is "based upon" or "substantially the same"[35] as those public disclosures. *See Glaser*, 570 F.3d at 920. The Seventh Circuit has found allegations to be "substantially similar" when the allegations were "parroted" publicly disclosed sources, added nothing "of value," or provided no

[33] Dkt. No. 38-1 ¶ 32; *see also* Dkt. No. 38 ¶ 22.

[34] Dkt. No. 38-1 ¶ 22 (emphasis added); *see also* Dkt. No. 38 ¶ 20.

[35] Prior to PPACA, the public disclosure bar applied to claims "*based upon* the public disclosure of allegations or transactions" in certain public sources. 31 U.S.C. § 3730(e)(4)(A) (pre-PPACA) (emphasis added). After PPACA, the bar was amended to apply "if *substantially the same* allegations or transactions as alleged in the action were publicly disclosed." 31 U.S.C. § 3730(e)(4)(A) (post-PPACA) (emphasis added). As noted above, the Seventh Circuit has not definitely decided which version of these statutes applies to Relator's claims. In any event, because the Seventh Circuit has interpreted the "based upon" language to mean "substantially similar to," the distinction may be one without a difference. *See Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 920 (7th Cir. 2009).

"genuinely new and material information." *See Rush Univ. Med. Ctr.*, 680 F.3d at 935-36. Relator's allegations are nothing of the sort.

As detailed above, Relator's eyewitness accounts provide more than the general notion of misconduct that can be gleaned from public sources. Relator describes, firsthand, Defendants' scheme to enhance its profits at the taxpayers' expense by "confusing" and misleading doctors to prescribe Plavix when it was unreasonable and unnecessary to do so.[36] These particularized allegations are not "virtually identical" to anything in the public domain. *See e.g.*, *Glaser*, 570 F.3d at 920 (finding allegations substantially similar where they are "virtually identical" to public-domain sources). And, tellingly, Relator does not rely on public sources in any way to make her allegations. *Cf. United States ex rel. Heath v. Wis. Bell, Inc.*, No. 08-CV-00724, 2012 WL 4128020, at *2 (E.D. Wis. Sept. 18, 2012) (finding that allegations were substantially similar where relator's complaint relied on the allegations in the public domain). Accordingly, based on this factor alone, Relator's claims fall outside the public disclosure bar.

C. Relator Has Direct And Independent Knowledge Of The Facts Of Defendants' Fraudulent Conduct.

Even if this Court finds that Relator's claims were "based upon" or "substantially similar as" public disclosures (which they are not), the public disclosure bar still does not apply to this case because Relator is an "original source" of the information. *See Glaser*, 570 F.3d at 916 ("The original-source exception permits jurisdiction over an FCA action *even if* the relator's lawsuit is based upon publicly disclosed information *provided* that the relator is an original source of the information." (emphasis added) (internal quotation marks and citation omitted)).

Indeed, the Supreme Court has implied that the main jurisdictional focus is on the "original source" requirement. *See id*. at 919-20. An "original source" is "an individual who has

[36] *See, e.g.*, Dkt. No. 38 ¶¶ 3, 19-21, 23, 32, 46-60; Dkt. No. 38-1 ¶¶ 18-19, 22, 29, 33, 36, 37.

direct and independent knowledge of the information on which the allegations are based."[37] 31 U.S.C. § 3730(e)(4) (pre-PPACA).[38] "Direct" knowledge can be derived from personal observations or personal involvement. *See Houck ex rel. United States v. Folding Carton Admin. Comm.*, 881 F.2d 494, 505 (7th Cir. 1989) (agreeing with the district court's conclusion that the relator's knowledge was direct as a result of his involvement in the activity). To establish "independent" knowledge, courts require that the relator be "someone who would have learned of the allegation or transactions independently of the public disclosure." *Glaser*, 570 F.3d at 321. Relator meets this standard.

The heart of Relator's allegations is that Defendants knowingly instructed their sales representatives to present false information to physicians and intentionally caused physicians to submit unreasonable and unnecessary prescriptions for Plavix which constituted false claims against the government. Relator's direct and independent knowledge of the information underlying such allegations stems solely from her position with Defendants, where she was trained as a sales representative to mislead doctors about Plavix. The scheme involved Defendants "mischaracteriz[ing] clinical studies"[39] and instructing their sales force to "confuse" physicians and promote a false narrative regarding Plavix's efficacy.[40] Relator's direct and independent knowledge of the deceptiveness of Defendants' marketing strategy results from the

[37] The statute also requires that a relator voluntarily provide the information to the government, but Relator's fulfillment of this requirement is not disputed. To be clear, Relator disclosed her allegations to the government before filing suit.

[38] As a part of PPACA, Congress also amended the "original source" exception. Under the current statute, "'original source' means an individual . . . who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under [the FCA]." 31 U.S.C. § 3730(e)(4)(B) (post-PPACA). Relator qualifies as an original source under this standard as well because Relator was the first person to inform the government that Defendants affirmatively knew the truth about Plavix, disregarded that truth, and engaged in a fraudulent scheme to use its sales force to dupe doctors into prescribing Plavix. *Cf. Osheroff*, 2012 WL 4479072, at *12 (determining that the relator was not an original source because the independent knowledge was relevant to the defendants' anticipated affirmative defenses, but not to the relator's actual claims).

[39] *See, e.g.*, Dkt. No. 38 ¶¶ 23, 58-60 ; Dkt. No. 38-1 ¶ 29.

[40] *See, e.g.*, Dkt. No. 38 ¶¶ 21, 59; Dkt. No. 38-1 ¶ 29.

discrepancies between her sales training about Plavix and her instructions on its promotion. For example, she received the CAPRIE Road Map for training purposes, which revealed Plavix's non-significant efficacy data, and yet was instructed by Defendants to promote Plavix in direct contradiction to the results.[41] Thus, Relator is an "original source" of the allegations in the SAC because she was personally involved in the scheme.

Defendants' reliance on *United States ex rel. Leveski v. ITT Educational Services., Inc.*, No. 1:07-CV-00867, 2011 WL 3471071 (S.D. Ind. Aug. 8, 2011), is misplaced.[42] In that case, the court found that the relator was not an original source primarily because the relator's deposition testimony contradicted the relator's own complaint and affidavit. *Id*. at *6. There, the relator's testimony revealed "her apparent lack of knowledge" regarding essential elements of the false claims. *Id*. It was because of the lack of direct and independent knowledge of facts "*related to the overall claim of fraud*" and intention to deceive the government that the relator did not qualify as an original source. *Id*. at *7 (emphasis added). Unlike in *ITT*, Relator here has direct and independent knowledge of the facts related to the overall claim of fraud.

Furthermore, Defendants' argument that Relator's counsel previously represented plaintiffs making similar allegations relies solely on cases in which the records are silent as to where the relator learned about fraudulent behavior apart from conversations with counsel.[43] In contrast, both the SAC and Relator's Affidavit explicitly state the source of Relator's knowledge

[41] *See* Dkt. No. 38-1 ¶¶ 15-16, 18.

[42] *See* Dkt. No. 44 at 18-20.

[43] See *Glaser*, 570 F.3d at 912 ("We have no idea how Lapointe learned of Wound Care's billing practices because both Glaser and Lapointe have invoked the attorney-client privilege to avoid revealing Lapointe's source."); *Shultz v. Devry Inc*., No. 07 C 5425, 2009 WL 562286, at *4 (N.D. Ill. Mar. 4, 2009) ("She did not have an understanding of Title IV or DeVry's program participation agreement until she spoke to [her attorney]. She first learned in a conversation with [her attorney] that DeVry allegedly violated the program participation agreement by compensating recruiters for enrollments, but refused to answer questions about this conversation in her deposition based on the attorney-client privilege."); *U.S. ex rel. Lopez v. Strayer Educ. Inc*., 698 F. Supp. 2d 633, 636-44 (E.D. Va. 2010) (containing extensive deposition testimony in which the relator repeatedly equivocated or denied knowledge of the pertinent allegations and determining the information was from Lopez's counsel, without ever reaching the "original source" argument).

regarding the allegations at dispute in this case: her position as a sales representative and the instructions she received from Defendants.[44] Similarly, Defendants' argument that because Relator works as a Sanofi sales representative, she does not have knowledge of BMS's wrongdoing is without merit. The SAC provides that Defendants "jointly administered" all efforts to promote Plavix, which means all of Relator's knowledge relates equally to both Defendants.[45]

Therefore, Relator's lawsuit is exactly what the *qui tam* provisions encourage. *See Glaser*, 570 F.3d at 919 ("The qui tam provisions of the FCA are designed to encourage persons with *first-hand* knowledge of fraudulent misconduct, or those who are either *close observers* or *otherwise involved* in the fraudulent activity to come forward." (internal quotation marks and citation omitted)). Relator witnessed firsthand Defendants' scheme, and her claims arise from her personal observations and involvement with the scheme. Accordingly, this Court should deny Defendants' motion to dismiss.

D. Defendants' Challenges Under The Public Disclosure Bar Are Mixed Questions Of Jurisdiction And Substantive Law That Are More Properly Considered Under A Motion For Summary Judgment.

At the motion-to-dismiss stage, most courts within the Seventh Circuit altogether ignore the appropriate standard for determining whether a relator has avoided the public disclosure bar. This is likely because although 31 U.S.C. § 3730(e)(4)(A) (pre-PPACA) uses the term "jurisdiction," the issue is one of "substantive law." *See, e.g., United States ex rel. Stone v. OmniCare, Inc.*, No. 09C4319, 2011 WL 2669659, at *6 (N.D. Ill. July 7, 2011); *United States ex rel. Gear v. Emergency Med. Assocs. of Ill., Inc.*, 436 F.3d 726, 728 (7th Cir. 2006). As the Supreme Court has noted, the public disclosure bar "speaks not just to the power of a particular

[44] *See, e.g.*, Dkt. No. 38 ¶¶ 16-17, 19; Dkt. No. 38-1 ¶¶ 4-5.
[45] Dkt. No. 38 ¶¶ 2-3.

court but to the substantive rights of the parties as well." *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 951 (1997); *see also Rockwell Int'l. Corp. v. United States*, 549 U.S. 457, 468 (2007) ("Indeed, we have already stated [in *Hughes Aircraft*] that § 3730(e)(4) speaks to the power of a particular court as well as the substantive rights of the parties.").

Recognizing this duality, courts within the Seventh Circuit have concluded that the "jurisdictional question is necessarily intertwined with the merits of the case"—particularly, Defendants' right to assert certain defenses to Relator's allegations.[46] *United States ex rel. Gear v. Emergency Med. Assocs. of Ill., Inc.*, No. 00C1046, 2004 WL 1433601, at *4 (N.D. Ill. June 25, 2004). Thus, Defendants' motion to dismiss is misplaced. Because Defendants rely on evidence outside Relator's complaint and affidavit, whether Relators' claims fall outside the public disclosure bar is more properly addressed as a summary-judgment motion.[47]

III. RELATOR'S CLAIMS SATISFY RULE 9(B).

Although claims brought under the FCA must satisfy the pleading standard of Rule 9(b), *Gross*, 415 F.3d at 604, when a plaintiff alleges fraud over an extended period of time, "the requirements of Rule 9(b) are tempered somewhat," *United States v. Pekin Mem'l Hosp.*, No. 05-cv-1018, 2008 WL 2705443, at *4 (C.D. Ill. July 9, 2008). *See also United States ex rel. Trombetta v. Emsco Billing Servs., Inc.*, Nos. 96 C 226, 99 C 151, 2002 WL 34543515, at *3 (N.D. Ill. Dec. 5, 2002) ("Where the allegedly fraudulent statements are numerous and occurred

[46] This is even more the case under the post-PPACA public disclosure bar, which eliminates the word "jurisdiction" and instead states that "[t]he court *shall dismiss an action* or claim" if the bar is triggered. 31 U.S.C. § 3730(e)(4)(A) (post-PPACA) (emphasis added). Accordingly, for Defendants' false claims submitted *after* March 23, 2010, the inquiry certainly is substantive, not jurisdictional, and a Rule 12(b)(1) motion therefore, is not the proper vehicle.

[47] If this Court exercises its discretion to convert Defendants' 12(b)(1) motion into one for summary judgment, Relator respectfully requests an opportunity to more fully brief this issue and to provide additional supporting evidence. *See United States ex rel. Stone v. OmniCare, Inc.*, No. 09C4319, 2011 WL 2669659, at *6 (N.D. Ill. July 7, 2011) (concluding it necessary to convert defendant's 12(b)(1) motion to a summary-judgment motion for the court to consider defendant's extrinsic evidence); *see also* Fed. R. Civ. P. 12(d) (requiring that all parties "be given a reasonable opportunity to present all the material that is pertinent to the motion"). Alternatively, the Court could consider the Defendants' motion under 12(b)(6), but in that case, the Court cannot consider Defendants' extrinsic evidence. *See* Fed. R. Civ. P. 12(d).

over a long period of time, the requirements of Rule 9(b) are less stringently applied."). Specifically, courts have found that it is impracticable and unreasonable under Rule 9(b) to require a plaintiff to provide every detail of an extensive, extended scheme of fraud. *Pekin Mem'l Hosp.*, 2008 WL 2705443, at *4; *see also Beiersdorf, Inc. v. Int'l Outsourcing Servs., LLC*, No. 07-C-888, 2008 U.S. Dist. LEXIS 36689, at *20-21 (E.D. Wis. Apr. 30, 2008). As one court has explained:

> While Rule 9(b) does apply to Act claims, and while there is a good deal of caselaw that speaks of a journalistic-type approach to its requirement of pleading "with particularity," that locution really does not fit well in dealing with extended fraudulent schemes involving large volumes of transactions—it must be remembered that what Rule 9(b) mandates particularity about are "the *circumstances* constituting fraud." Hence such cases as *Midwest Grinding Co. v. Spitz*, 976 F.2d 1016, 1020 (7th Cir. 1992) have held that a plaintiff is required to provide only a "general outline" of the alleged scheme sufficient to put defendants on notice about their roles in the fraudulent or false activity.

United States ex rel. Salmeron v. Enter. Recovery Sys., Inc., 464 F. Supp. 2d 766, 768 (N.D. Ill. 2006).

Here, Relator alleges an extensive scheme by Defendants to defraud the government that has been ongoing since 1996. As such, the SAC details the who, what, when, where, and how of the "general outline" of the fraudulent scheme, thereby satisfying Rule 9(b).[48]

A. Relator Alleges "The Who."

The SAC specifically names each perpetrator of the fraud: Bristol Myers Squibb, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc.[49] In addition, using

[48] Defendants would like the Court to believe that Relator's claims must be dismissed if Relator does not identify a specific claim submitted to the government for reimbursement. Dkt. No. 44 ¶ 23. This is not the standard. Relator is not required to point to a single specific claim submitted to Medicare or Medicaid in order to survive a motion to dismiss. *See United States v. Ukrainian Vill. Pharmacy, Inc.*, No. 09 C 7891, 2012 WL 4742827, at *7 (N.D. Ill. Sept. 5, 2012) (disagreeing "that because Relator cannot point to a single specific bill submitted to the government, his action regarding copayments necessarily fails"); *United States ex rel. Coots v. Reid Hosp. & Health Care Servs., Inc.*, No. 1:10-cv-0526-JMS-TAB, 2012 WL 1098930, at *2 n.4 (S.D. Ind. Apr. 2, 2012) (noting that the Seventh Circuit did not hold that a relator is required to identify at least one false claim actually submitted). Relator has alleged sufficient other detail to meet the Rule 9(b) standard.

Relator as a specific example, the SAC alleges that *members of the sales force* were instructed by Defendants to promote Plavix as having certain characteristics known by Defendants to be untrue, which thereby resulted in false claims.[50] For instance, Defendants instructed their sales force, including Relator, to promote Plavix as being superior to aspirin for certain indicated uses and comparably safe, when it was not.[51]

As this Court has found, allegations that a defendant's "sales representatives and sales managers" participated in the fraud is sufficient to meet the "who" requirement. *United States ex rel. Liotine v. CDW Gov't*, No. 05-33-DRH, 2009 WL 3156704, at *4 (S.D. Ill. Sept. 29, 2009). The SAC sufficiently sets forth the parties involved in the FCA violations, thereby fulfilling the "who" prong of the specificity requirements.

B. Relator Alleges "The What" And "The How."

The SAC alleges that Defendants: (1) unjustifiably promoted Plavix, through their sales representatives (including Relator), to physicians as superior to aspirin for patients who had recently suffered strokes or myocardial infarctions; (2) misrepresented to physicians, through their sales representatives (including Relator), that Aggrenox was inferior to Plavix; and, (3) as a result of these actions, caused physicians to submit false claims to the government.[52] In other words, Relator pleads *what* fraudulent scheme she is alleging and *how* the fraudulent scheme was carried out. This is sufficient to satisfy Rule 9(b)'s pleading requirement. *See United States ex rel. Dismissed Relator v. Lilwani*, No. 11-3276, 2012 WL 4739922, at *6 (C.D. Ill. Oct. 3, 2012); *United States ex rel. Dismissed Relator v. Veytsman*, No. 11-3281, 2012 U.S. Dist. LEXIS

[49] Dkt. No. 38 ¶¶ 3, 15, 19-23, 32-35, 46-78.
[50] Dkt. No. 38 ¶¶ 19-21, 51, 60.
[51] Dkt. No. 38 ¶¶ 19-20, 51, 54.
[52] Dkt. No. 38 ¶¶ 3, 19-23, 46-78.

144146, at *26 (C.D. Ill. Sept. 24, 2012). Defendants' fraudulent scheme, as alleged by Relator in the SAC, is detailed below.

1. Defendants fraudulently promoted Plavix as superior to aspirin.

As described in the SAC, Defendants knew their claims that Plavix was superior to aspirin were false, but nevertheless promoted Plavix as such.[53] The 1996 CAPRIE study, for example, "demonstrated [in the recent stroke and recent myocardial infarction subgroups] that there was no statistically significant reduction in the primary endpoint for patients taking Plavix as compared to patients taking aspirin."[54] And, in 2001, the FDA's Division of Drug Marketing and Communications ("DDMAC") sent Defendants a letter stating that their promotions were misleading as they "suggest that Plavix is superior to aspirin when such has not been demonstrated by substantial evidence."[55] Yet, instead of informing health care professionals of this information, Defendants manipulated clinical trial data to support their false claims regarding Plavix's characteristics. For instance:

- "On [Defendants'] pamphlets provided to physicians summarizing the CAPRIE study, the subgroup analysis [demonstrating that Plavix was not superior to aspirin] was not provided."[56]
- "[C]ompany sales pamphlets (citing CAPRIE) claimed that there was 'proven efficacy' of Plavix over aspirin in ischemic stroke patients[,]"[57] which was false.
- "[Defendants] ordered its sales personnel to promote Plavix as being superior to aspirin in stroke patients[, which was false]. As a result, Plavix was regularly and systematically presented to physicians as superior to aspirin for treatment of stroke patients."[58]
- "[Defendants] also misled physicians regarding the efficacy of Plavix plus aspirin dual therapy following coronary artery bypass grafting ("CABG"). Upon information and belief, [Defendants] obtained a label change for Plavix based on [the CURE trial] to

[53] Dkt. No. 38 ¶¶ 3, 8-12, 19-20, 47-53.
[54] Dkt. No. 38 ¶ 49.
[55] Dkt. No. 38 ¶¶ 8-12.
[56] Dkt. No. 38 ¶ 49.
[57] Dkt. No. 38 ¶ 50.
[58] Dkt. No. 38 ¶ 51.

indicate that Plavix was effective for treatment [of] post-CABG. However, . . . [n]o benefit was seen for [Plavix] use after CABG in the CURE trial."[59]

- "[Defendants] ordered its sales force to promote Plavix as comparably safe to aspirin based on the CAPRIE study even though the CAPRIE study compared Plavix to a more toxic dose of aspirin that is not regularly prescribed today."[60]

- "The results of the Chan Study were not disclosed [by Defendants] to prescribing neurologists."[61]

2. Defendants misrepresented that Aggrenox was inferior to Plavix.

The PRoFESS study "'showed no difference in stroke recurrence among patients assigned to [Plavix] compared with patients assigned to [Aggrenox],'" and "'[t]here was also no statistically significant difference between the two drugs in causing major hemorrhagic events.'"[62] Despite this fact, Defendants instructed their sales force, including Relator, to present the PRoFESS data in a manner designed to confuse and trick physicians into believing that Aggrenox was inferior to Plavix.[63] That is, they instructed their sales force to emphasize that "it should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients."[64] Such statements were designed to be intentionally misleading.

3. Defendants' conduct caused false claims to be submitted.

In furtherance of their fraudulent scheme, Defendants "targeted doctors whose patients rely on Government Payors for health care treatment so as to wrongfully inflate sales and profits at a tremendous cost to American taxpayers."[65] The purpose of targeting such doctors was based on the "physicians' inherent willingness to prescribe more expensive drugs to patients who relied

[59] Dkt. No. 38 ¶ 53 (reference added).
[60] Dkt. No. 38 ¶ 54.
[61] Dkt. No. 38 ¶ 55. The SAC is not confined to these general allegations, but also details Relator's personal experience in the SAC and her attached affidavit, which includes being "instructed by Sanofi" to "regularly promote[] Plavix as having certain characteristics that BMS/Sanofi knew were not true." Dkt. No. 38 ¶¶ 19-20; *see also* Dkt. No. 38-1 ¶¶ 18-19, 22.
[62] Dkt. No. 38 ¶ 59.
[63] Dkt. No. 38 ¶¶ 21, 58-60.
[64] Dkt. No. 38 ¶¶ 21, 60. Again, the SAC also details Relator's own personal experience related to this portion of Defendants' fraudulent scheme. Dkt. No. 38 ¶ 21; *see also* Dkt. No. 38-1 ¶¶ 29, 31.
[65] Dkt. No. 38 ¶¶ 22-23; *see also* Dkt. No. 38-1 ¶ 32.

on government assistance in obtaining prescription medication."[66] By making fraudulent claims regarding Plavix's efficacy, Defendants convinced physicians of Plavix's false superiority and left many physicians with the false impression that Plavix was the only option for them to prescribe.[67] These actions resulted in physicians submitting false claims to the government.[68]

C. Relator Alleges "The When."

The SAC states that since 1996, when the CAPRIE study was published, Defendants have falsely promoted Plavix as superior to aspirin.[69] Defendants engaged in such promotion, through their sales force and materials provided to physicians, despite the fact that the CAPRIE study did not support such a claim, and still do so today.[70]

Further, the SAC details specific dates on which Defendants' had knowledge of the falsity of their Plavix assertions. For instance, the SAC describes: (1) the 2001 DDMAC letter sent to Defendants stating that Defendants' "sales aid overstated the efficacy of Plavix, made unsubstantiated superiority claims, constituted a misleading efficacy presentation, and lacked fair balance";[71] (2) the January 20, 2005 Chan Study showing that Plavix caused "significantly more gastrointestinal bleeding";[72] and (3) the 2008 study negating Plavix's alleged inferiority to Aggrenox (aspirin + dipyridamole).[73] Nevertheless, Defendants continued their illegal and deceptive promotion of Plavix.

Finally, the SAC provides the specific time frames in which Relator, herself, was involved in Defendants' fraudulent scheme. Relator began working for BMS in 1999 and took a

[66] Dkt. No. 38 ¶¶ 22, 61; *see also* Dkt. No. 38-1 ¶ 33.
[67] Dkt. No. 38 ¶ 62; *see also* Dkt. No. 38-1 ¶¶ 36-37.
[68] Dkt. No. 38 ¶¶ 63, 70, 71, 75-77; *see also* Dkt. No. 38-1 ¶ 38.
[69] Dkt. No. 38 ¶¶ 32, 47-52, 55.
[70] *See* Dkt. No. 38 ¶¶ 20, 47-52, 55.
[71] Dkt. No. 38 ¶¶ 8-12.
[72] Dkt. No. 38 ¶¶ 20, 54-55. Additional studies in 2011 and early 2012 indicated that Plavix may pose a greater bleeding risk than aspirin, yet Defendants have not altered their promotional materials to reflect such conclusions. Dkt. No. 38 ¶¶ 56-57.
[73] Dkt. No. 38 ¶¶ 21, 58-60.

sales position with Sanofi in 2003.[74] Relator received training for the selling of Plavix beginning in 2003.[75] During the course of her employment with Defendants, Relator was instructed to promote Plavix as having certain characteristics that Defendants knew were untrue, to misrepresent and withhold certain studies, and to target physicians who wrote significant numbers of prescriptions for patients covered by Government Payors.[76]

As courts have previously held, when the alleged conduct occurs over a long period of time, the complaint must only specify a general time frame during which the fraud occurred. *United States ex rel. Hunt v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 437 (E.D. Pa. 2004); *see also United States ex rel. Budike v. PECO Energy*, No. 07-4147, 2012 WL 4108910, at *10 (E.D. Pa. Sept. 14, 2012) ("Although Relator does not provide many specific dates in the Amended Complaint, he adequately alleges 'when' the FCA violations occurred. These violations occurred from September 4, 2003 to 2007."). The SAC does this and more. Here, Relator alleges that since 1996, Defendants have knowingly presented physicians with false information regarding the efficacy of Plavix compared to cheaper alternatives such as aspirin and have manipulated, misrepresented, and/or withheld clinical data from physicians in order to convince physicians to prescribe Plavix. This is sufficient.

D. Relator Alleges "The Where."

The SAC alleges that Defendants' co-marketed Plavix in the United States.[77] Further, the SAC makes clear the place at issue is anywhere in the United States where Defendants marketed and sold the drug Plavix. More specifically, Relator lists several places as representative examples of locations where the false claims occurred. For instance, the SAC lists claims in

[74] Dkt. No. 38 ¶ 16; *see also* Dkt. No. 38-1 ¶¶ 3-6.
[75] Dkt. No. 38 ¶ 17; *see also* Dkt. No. 38-1 ¶ 6.
[76] Dkt. No. 38 ¶¶ 19-22; *see also* Dkt. No. 38-1 ¶¶ 18-19, 22, 29, 31-38.
[77] Dkt. No. 38 ¶¶ 1, 31.

Illinois, California, Delaware, District of Columbia, Florida, Hawaii, Nevada, Tennessee, Texas, Virginia, Georgia, Indiana, Michigan, Montana, New Mexico, New York, Massachusetts, City of Chicago, New Jersey, Rhode Island, Wisconsin, Oklahoma, North Carolina, Minnesota, Colorado, and Connecticut.[78] Moreover, Relator's affidavit clearly specifies that Relator was trained and instructed by Defendants regarding Plavix in St. Louis and Dallas.[79] Identifying the state and/or city where Defendants' conduct occurred is sufficient to satisfy the standards of Rule 9(b). *See United States ex rel. Estrada v. Quad City Prosthetic, Inc.*, No. 06-4015, 2011 WL 3273142, at *5 (C.D. Ill. Aug. 1, 2011).[80]

* * *

In this case, Relator has sufficiently alleged the "who, what, when, where, and how" of the circumstances constituting fraud.[81] Defendants' motion to dismiss should be denied.[82]

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[78] Dkt. No. 38 ¶¶ 36, 39 79-290 (specifically discussing Defendants' actions in Illinois).

[79] Dkt. No. 38-1 ¶ 6; *see also* Dkt. No. 38 ¶ 17.

[80] This is not a situation where Relator has provided no locations at all. *Cf. Nichols Motorcycle Supply, Inc. v. Dunlop Tire Corp.*, No. 93 C 5578, 1994 WL 113108, at *3 (N.D. Ill. Mar. 30, 1994) (finding Rule 9(b) unsatisfied where no location was given). Instead, Relator has provided representative examples of the "where" the circumstances surrounding the fraud occurred. This is enough. *See United States ex rel. Turner v. Michaelis Jackson & Assocs., L.L.C.*, No. 03-cv-4219-JPG, 2007 WL 496384, at *4 (S.D. Ill. Feb. 13, 2007) (holding that a few representative examples is sufficient).

[81] Relator similarly has sufficiently alleged the "who, what, when, where, and how" of Relator's conspiracy allegation. Relator has alleged an agreement between Defendants to co-market Plavix through fraudulent promotions and to train and instruct Defendants' sales force to confuse and misinform physicians to increase the number of Plavix prescriptions submitted to Government Payors, thereby causing false claims to be submitted to the government. Dkt. No. 38 ¶¶ 1-3, 15-19-23, 32, 46, 49-53, 55, 59-63, 75-77; Dkt. No. 38-1 ¶¶ 6, 15-19, 22, 29, 31-38. Defendants have sufficiently outlined the contours of Defendants' conspiracy. *Cf. Gross v. AIDS Research Alliance-Chi.*, No. 01 C 8182, 2004 WL 905952, at *3 (N.D. Ill. Apr. 27, 2004) (explaining that defendant's motion to dismiss was granted because relator did not even allege the "contours" of the conspiracy).

[82] Defendants separately allege that Relator's claims under the City of Chicago False Claims Act and the Illinois Public Assistance Fraud Act are deficient. *See* Dkt. No. 44 ¶ 25 nn. 31-31. Relator acknowledges that the Illinois Public Assistance Fraud Act does not provide a private right of action, and therefore, respectfully requests that the Court dismiss its fourth cause of action without prejudice. Dkt. No. 38 ¶¶ 85-89. However, Defendants are incorrect with respect to the City of Chicago False Claims Act. Relator need not specifically use the words "city contractor" to allege a claim under the City of Chicago False Claims Act. City contractor is defined as a "a person who enters into a contract" with the city. Chicago Mun. Code § 1-22-010. Relator pleaded that "Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Chicago City Government to approve and pay such false and fraudulent claims." Dkt. No. 38 ¶ 216. There was a contract between the City and healthcare providers for reimbursement. If there were not, why would doctors submit claims in receipt of payment?

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied.[83]

Respectfully submitted,

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[83] Defendants would like the Court to believe that because the government has declined to intervene at this time, this case is without merit. Defendants are mistaken. The "fact that the government has declined to intervene in any given *qui tam* action does not diminish the federal interest in combating fraud against the government." *United States ex rel. Landsberg v. Levinson*, No. 2:03CV1429, 2006 WL 895044, *4 (W.D. Pa. Mar. 29, 2006). Indeed, the government's involvement still continues. *See Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 754 (5th Cir. 2001) (en banc) (explaining that after declining to intervene, the government, in addition to other things, may request that it be served with copies of pleadings and will still receive the "larger share of any recovery").

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I hereby certify that on January 24, 2013, a true and correct copy of the foregoing was filed electronically with the Clerk of the United States District Court and forwarded electronically to all counsel:

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